K102505

510(k) SUMMARY (as required by 21 CFR 807.92) В.

High Tibial Osteotomy (HTO) Plating System

November 15, 2010

NOV 2 4 -2010

COMPANY:

Aesculap Implant Systems, LLC

3773 Corporate Parkway Center Valley, PA 18034

Establishment Registration Number: 3005673311

CONTACT:

Kathy A. Racosky

(610) 984-9291 (phone) 610-791-6882 (fax)

TRADE NAME:

HTO Plating System

COMMON NAME:

High Tibial Osteotomy (HTO) Plating System

CLASSIFICATION NAME: Plate, Fixation, Bone (HRS)

Screw, Fixation, bone (HWC)

REGULATION NUMBER: 888.3030, 888.3040

SUBSTANTIAL EQUIVALENCE

Aesculap Implant Systems, LLC believes that the new HTO Maxi plate and screws are substantially equivalent to the existing plate and screws of the High Tibial Osteotomy (HTO) Plating System cleared under K080992.

DEVICE DESCRIPTION

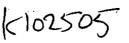
The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System which consists of tapered plates, screws (cancellous and cortical design), and spacer blocks in various sizes. The plate in this system accepts 6 mm cancellous screws proximally and 4.5 mm cortical screw distally. The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System is manufactured from Titanium/Titanium Alloy and will be provided sterile.

INDICATIONS FOR USE

There have been no changes to the Indications for Use. It remains as follows:

The Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System is intended to be used in conjunction with bone screws to provide fixation following Proximal Tibial opening wedge osteotomies.

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PURPOSE FOR PREMARKET NOTIFICATION

The purpose for this submission is to gain marketing clearance for the new HTO Maxi Plate and screws which are being added to the Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The Aesculap Implant Systems HTO Plating System is considered substantially equivalent to other legally marketed predicate systems. Biomechanical testing of the subject device was found to be similar in performance to previously cleared high tibial osteotomy systems with similar indications.

PERFORMANCE DATA

Fatigue testing of the Position HTO Maxi Plate was performed to support substantial equivalence.

DEPARTMENT OF HEALTH & HUMAN SERVICES





Food and Drug Administration 10903 New Hampshire Avenue Document Control Room –WO66-G609 Silver Spring, MD 20993-0002

Aesculap Implant Systems, LLC % Ms. Kathy Racosky Regulatory Affairs Specialist 3773 Corporate Parkway Center Valley, Pennsylvania 18034

NOV 2 4 2010

Re: K102505

Trade/Device Name: Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating

System

Regulation Number: 21 CFR 888.3030

Regulation Name: Single/multiple component metallic bone fixation appliances and

accessories

Regulatory Class: Class II

Product Code: HRS

Dated: November 15, 2010 Received: November 17, 2010

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the <u>Federal Register</u>.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson

Director

Division of Surgical, Orthopedic and Restorative Devices Office of Device Evaluation Center for Devices and

Radiological Health

Enclosure

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510(k) Number: K/0 2505	NOV 2 4 2010		
Device Name: Aesculap Implant Systems High Tibial Osteotomy (HTO) Plating System			
Indications for Use:			
	al Osteotomy (HTO) Plating System is intended to to provide fixation following Proximal Tibial opening		
Prescription Use X and/or	Over-the-Counter Use		
(Part 21 CFR 801 Subpart D)	(21 CFR 801 Subpart C)		
(PŁEASE DO NOT WRITE BELOW THIS I	LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)		
	Office of Device Evaluation (ODE)		
(Division Sign-Off) Division of Surgical, Ordand Restorative Devices	thopedic,		

510(k) Number <u>K102505</u>